K112748

SPINAL USA

2050 Executive Drive
Pearl, MS 39208

Ph: 601-420-4244 Fax: 601-420-5501

JUL 11 2012

510(k) Summary

Date Summary Prepared:	July 18, 2011
Submitter Information:	Spinal USA 2050 Executive Drive Pearl, MS 39208
Contact Name:	Frankie Cummins
Phone:	601-420-4244
Fax:	601-420-5501
E-mail:	fc@spinalusa.com
Device Trade Name:	Slimplicity Solo Anterior Cervical Plate System
Common Name:	Spinal Intervertebral Body Fixation Orthosis
Regulatory Number:	888.3060
Classification:	Class II
Product Code:	KWQ

INTENDED USE:

The Slimplicity Solo Anterior Cervical Plate System is intended for anterior cervical fixation to the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

DEVICE DESCRIPTION:

The Slimplicity Solo Anterior Cervical Plate System consists of an assortment of plates and screws. Each Slimplicity Solo plate attaches to the anterior portion of the vertebral body of the cervical spine (levels C2-C7). Slimplicity Solo implants are composed of titanium alloy, as specified in ASTM F136. The components will be provided non-sterile.

K112748

MECHANICAL TESTING:
The Slimplicity Solo Anterior Cervical Plate System was mechanically tested per ASTM F1717. The objective of this test battery is to mechanically test the Slimplicity Solo Anterior Cervical Plate System using the following test methods:

Static Axial Compression Bending testing in a load to failure mode
Static Torsion testing in a load to failure mode
Cyclical axial compression testing to estimate the maximum run out load value at 5,000,000 cycles

Mechanical Test Conclusion:

The Slimplicity Solo Anterior Cervical Plate System is as safe as the predicates based on the following:

1) The design of the Slimplicity Solo Anterior Cervical Plate System is similar to the predicates in thickness, width, and length.
2) The Slimplicity Solo Anterior Cervical Plate System bone screw is similar to the predicates in type, size, and length.
3) The material used in the Slimplicity Solo Anterior Cervical Plate System is the same as used in the predicate systems.
4) The mechanical strength of the Slimplicity Solo Anterior Cervical Plate System is substantially equivalent to the predicate based on mechanical test results. The Slimplicity Solo Anterior Cervical Plate System test results are provided in section 18 of this 510(k) submittal. Mechanical strength substantial equivalence to predicates is shown in section 12.

The Slimplicity Solo Anterior Cervical Plate System is as effective as the predicate based on the following:

1) The intended use of the Slimplicity Solo Anterior Cervical Plate System is the same as the predicates.
2) The indication for use of the Slimplicity Solo Anterior Cervical Plate System is the same as the predicates.

The Slimplicity Solo Anterior Cervical Plate System is as safe and effective as its predicates.

EQUIVALENT DEVICE:
Documentation was provided which demonstrated the Slimplicity Solo Anterior Cervical Plate System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.

The overall design of the Slimplicity Solo Anterior Cervical Plate System consists of plates and bone screws. The components are available in a variety of lengths in order to accommodate patient anatomy and are substantially equivalent to the predicate devices.

Components of the Slimplicity Solo Anterior Cervical Plate System are similar to the predicate systems. The size and shape of the plate of the Slimplicity Solo Anterior Cervical Plate System and predicate systems are similar. The Slimplicity Solo Anterior Cervical Plate System bone screw thread type, size and length are similar to the predicates. Material of both the plate and screws is the same as the predicates. Sterilization is the same as the predicates.

Predicate Devices:
Uniplate Anterior Cervical Plate System K042544
Synthes Anterior CSLP System K030866
Synthes Vectra-One System K071667

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spinal USA, LLC
% Mr. Frankie Cummins
Engineering Manager
2050 Executive Drive
Pearl, Mississippi 39208

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Re: K112748
Trade/Device Name: Slimplicity Solo Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: July 05, 2012
Received: July 05, 2012

Dear Mr. Cummins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112748

Indications for Use

510(k) Number (if known): K112748

Device Name: Slimplicity Solo Anterior Cervical Plate System

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112748

Pg 1 of 1